FEB 2 6 2003

Heraeus

K022251
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510(k) Summary

Applicant's name and address	Heraeus Kulzer GmbH & Co. KG Grüner Weg 11 D-63450 Hanau
Contact persons	Dr. K.-D. Kühn phone: +49 6081 959-264 fax: +49 6081 959-288 klaus-dieter.kuehn@heraeus.com Dr. C. Tuchscherer phone: +49 6081 959-278 fax: +49 6081 959-288 christian.tuchscherer@heraeus.com
Date of summary	28.5.2002
Device trade name	PALABOND®
Classification name	Bone Cement
Identification of the marketed device Palacos® to which equivalence is claimed	PALACOS® R BONE CEMENT PMA Number: P810020
Description of the device	Palabond® is an acrylic bone cement for use in orthopedic surgery. It is formed from powder and liquid by exothermic polymerization. It secures the fixation of the grafted artificial joint improving the transfer of forces at the interface implant-bone.
Intended use	Fixation of prostheses in the bone (partial or total hip joint replacement at the hip, knee or other joints).
Comparison of technological characteristics	Palabond® is chemically identical to the well known Palacos® R being marketed for more than 25 years implicating the same biocompatibility. The only difference is the addition of bigger particles (granules) of copolymer to the powder. The mechanical performance is equivalent (see test report).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Dr. K.D. Kuhn
Heraeus Kulzer GmbH & Co. KG
Gruner Weg 11
D-63450 Hanau

Re: K022251
Trade Name: Palabond
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: December 12, 2002
Received: December 16, 2002

Dear Dr. K.D. Kuhn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022251

Device Name: PALABOND®

Indications For Use:

PALABOND is intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

Division Sign-Off

Division of General, Restorative and Neurological Devices

510(k) Number K022251

(Optional Format 3-10-98)